

8EHQ-0303-15302₅

March 10, 2003

Via Certified Mail/Return-Receipt Requested

CONTAINS CONFIDENTIAL
BUSINESS INFORMATION

TSCA Document Control Center
Mail Code 7407M
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460



COMPANY SANITIZED

Attn.: TSCA Section 8(e)

Re: TSCA Section 8(e) Submission for []

Dear Sir/Madam:

[] ([] or the Company) submits this letter and the enclosed study summary pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). This information is being provided in order to inform the U.S. Environmental Protection Agency (EPA or the Agency) of results from an acute oral toxicity test in rats that was conducted in [] for the chemical mixture identified by the trade name, []. Presented here is the English summary, based on the [] test report located in [] on this material.

The Company has not made a determination as to whether a significant risk of injury to human health or the environment is actually presented by these findings. Rather, this information is submitted in order to ensure that the EPA Administrator is adequately informed of such information.



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BUSINESS INFORMATION**

[] claims certain information in this Section 8(e) submission as confidential business information (CBI). In particular, the Company claims the company identity and the product trade name as CBI. To this end, [] provides herein two copies of the study summary – a confidential version and a sanitized version. In addition, [] also provides substantiation concerning the Company's claims of confidentiality. [] notes that the specific chemical identity information is not being claimed as CBI.

If there are any questions regarding this submission, please contact []
[]. He is reachable at []. Thank you for your
consideration in this matter.

Sincerely,

[]

Enclosures:

- Study summary – acute oral toxicity test (*confidential* version)
- Study summary – acute oral toxicity test (*sanitized* version)
- Substantiation of confidentiality claims

Title: "Acute oral toxicity test of [] in rats"

(Document prepared in Japanese)

[] Study No. A2450

Summary

[] was administered by single oral gavage to male and female Crj:CD (SD) rats at dose levels of 5, 50 500 and 2000 mg/kg. No animal was found dead at dose levels of 50 mg/kg and below. But, four out of five males and three out of five females were found dead at 500 mg/kg. In both sexes at 2000 mg/kg, all animals (five males and five females) were found dead. LD₅₀ value was estimated 50~500 mg/kg for males and ca.500 mg/kg for females. In clinical signs, prone position, clonic convulsion, ataxic gait, bradypnea, irregular respiration, ptosis, ocular discharge and salivation were observed at 500 mg/kg and above. In body weights, no obvious effects related to the test substance administration were noted. In necropsy, red foci in mucosa of glandular stomach, and brown fluid retention in stomach and small intestine were observed in the animals found dead. And, there were no obvious effects related to the test substance administration were observed in the survived animals.

Composition/Information on Ingredients

COMPONENT	CAS No.	%
Tetramethylammonium hydroxide(10%solution)	75-59-2	ca.96%
Alkylalcohol	Trade secret	ca. 4%

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED

**Substantiation of Confidentiality Claims for Sumitomo Chemical
America, Inc.'s TSCA Section 8(e) Submission on Repts-321C4**

March 10, 2003

1. *For what period of time do you assert this claim of confidentiality? If a claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why the information should remain confidential until such time or event?*

The scope of confidentiality claims pertains to: (a) company identity and (b) product trade name. We request that the asserted claims of confidentiality be maintained without time limitation. This information is considered proprietary and should remain so as long as the product is manufactured and imported. EPA will note that Sumitomo Chemical America (the Company) has elected *not* to claim the chemical identities in this product as confidential and as such the submitted Section 8(e) report discloses the specific chemical identities.

While the Company takes measures to protect the disclosure of the chemical identities, it discloses this information herein in an effort to promote awareness of health and safety information. In addition, the Company understands that EPA prefers that companies disclose chemical identity information in Section 8(e) submissions for this same reason.

The Company's claims are made to protect the proprietary linkage between the identity of Sumitomo Chemical America (and its parent company, Sumitomo Chemical Company) and the specific chemical identities. Sumitomo Chemical America requests that the company identity and trade name be kept confidential since any linkage of this information to the specific chemical identities could enable a competitor to develop similar products in the same application without having to undertake the same substantial R&D, technological, regulatory, production, and marketing efforts.

2. *Have there been any confidentiality determinations made by EPA, other Federal agencies, or courts in connections with this information? If so, please enclose copies.*

No.

3. *Has the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?*